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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,987	04/06/2007	Khalil Arar	120361	9438
27148	7590	10/01/2009	EXAMINER	
POL SINELLI SHUGHART PC			CALAMITA, HEATHER	
700 W. 47TH STREET				
SUITE 1000			ART UNIT	PAPER NUMBER
KANSAS CITY, MO 64112-1802			1637	
			MAIL DATE	DELIVERY MODE
			10/01/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/560,987	ARAR, KHALIL	
	<b>Examiner</b>	<b>Art Unit</b>	
	HEATHER G. CALAMITA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 July 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-38 is/are pending in the application.  
 4a) Of the above claim(s) 1-10, 12, 16, 25, 28 and 32 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 11, 13-15, 17-24, 26, 27, 29-31 and 33-38 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/15/2008</u> .   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group II, claims 11-38 and the species of claims 13, 15, 26, 29 and 31 in the reply filed on July 24, 2009, is acknowledged. The traversal is on the ground(s) that the inventions are not patentably distinct and there is no search burden. This is not found persuasive because this case is a national stage entry of a PCT, therefore search burden is not a factor for restriction rather unity of invention. Unity of invention was broken in the requirement mailed May 28, 2009, as it was established that no special technical feature linked the claimed inventions.

The requirement is still deemed proper and is therefore made **FINAL**.

### ***Status of Application, Amendments, and/or Claims***

2. Claims 1-38 are currently pending. Claims 1-10, 12, 16, 20, 25, 28, 32 and 34 are withdrawn as being directed to non-elected subject matter. Claims 11, 13-15, 17-24, 26, 27, 29-31, 33 and 35-38 are under examination.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims rejected under 35 U.S.C. 102(a) as being anticipated by Uguzzoli et al. (Analytical Biochemistry, 2004).

The only difference between instant claims 11 and 24 is that claim 24 is a multiplex assay therefore the claims will be addressed together in the rejection with reference to the multiplex assay.

With regard to claims 11 and 24, Uguzzoli et al. teach a method for detection or quantification of a nucleic acid analyte comprising the steps of

- a) providing a pair of nucleic acid probes, wherein said probes differ in their nucleic acid sequences and wherein the probes collectively include at least one monomeric LNA moiety and are collectively derivatized with two or more non-identical covalently attached dyes, wherein at least one dye is fluorescent and wherein each probe comprises at least one of the dyes (see the abstract and p. 145 col. under *LNA probe design and synthesis* and under *Design of LNA probes for allelic discrimination*)
- b) contacting the pair of nucleic acid probes with the nucleic acid analyte so as to allow for the hybridization of the pair of nucleic acid probes with the nucleic acid analyte in such a way that both probes are hybridized to adjacent segments of the target sequence of the nucleic acid analyte (see p. 145 col. 2 under *FVLIG20210A genotyping by the multicolor LNA probe assay* and p. 146 col. 1 under *Detection of the  $\beta^A$  and  $\beta^S$  allelic variants with a two color 5' nuclease assay*)
- c) measuring the change in the fluorescence of the pair of nucleic acid probes that is related to the hybridization of the nucleic acid probe with the nucleic acid analyte (see p. 145 col. 2 under *FVLIG20210A genotyping by the multicolor LNA probe assay* and p. 146 col. 1 under *Detection of the  $\beta^A$  and  $\beta^S$  allelic variants with a two color 5' nuclease assay*)

With regard to claims 13 and 26, Uguzzoli et al. teach the pair of nucleic acid probes comprises a donor dye and an acceptor dye which are able to jointly constitute a FRET system (see p. 145 col. under *LNA probe design and synthesis* and under *Design of LNA probes for allelic discrimination*)

With regard to claims 14 and 30, Uguzzoli et al. teach the method is carried out as a homogeneous assay to detect or quantify a nucleic acid in a sample (see p. 145 col. 2 under *FVLIG20210A genotyping by the multicolor LNA probe assay* and p. 146 col. 1 under *Detection of the  $\beta^A$  and  $\beta^S$  allelic variants with a two color 5' nuclease assay*)

With regard to claims 15 and 31, Uguzzoli et al. teach the change in the fluorescence occurs upon the hybridization of the nucleic acid probe with the nucleic acid analyte (see p. 145 col. 2 under *FVLIG20210A genotyping by the multicolor LNA probe assay* and p. 146 col. 1 under *Detection of the  $\beta^A$  and  $\beta^S$  allelic variants with a two color 5' nuclease assay*)

With regard to claims 17 and 33, Uguzzoli et al. teach the homogeneous assay is PCR (see p. 145 col. 2 under *FVLIG20210A genotyping by the multicolor LNA probe assay* and p. 146 col. 1 under *Detection of the  $\beta^A$  and  $\beta^S$  allelic variants with a two color 5' nuclease assay*)

With regard to claims 18 and 35, Uguzzoli et al. teach the probe functions as a hybridization probe in a PCR providing for a real-time detection or quantification of the amplification product (see p. 145 col. 2 under *FVLIG20210A genotyping by the multicolor LNA probe assay* and p. 146 col. 1 under *Detection of the  $\beta^A$  and  $\beta^S$  allelic variants with a two color 5' nuclease assay*)

With regard to claim 19, Uguzzoli et al. teach the nucleic acid probe is adapted for use as a molecular beacon (see p. 145 col. 2 under *FVLIG20210A genotyping by the multicolor LNA probe assay* and p. 146 col. 1 under *Detection of the  $\beta^A$  and  $\beta^S$  allelic variants with a two color 5' nuclease assay*)

With regard to claims 21 and 36, Uguzzoli et al. teach the probe is adapted for use as a Taqman probe in the LightCycler (see p. 145 col. 2 under *FVLIG20210A genotyping by the multicolor LNA probe assay* and p. 146 col. 1 under *Detection of the  $\beta^A$  and  $\beta^S$  allelic variants with a two color 5' nuclease assay*)

With regard to claim 22 Uguzzoli et al. teach, the method is multiplexed (see p. 145 col. 2 under *FVLIG20210A genotyping by the multicolor LNA probe assay* and p. 146 col. 1 under *Detection of the  $\beta^A$  and  $\beta^S$  allelic variants with a two color 5' nuclease assay*)

With regard to claims 27 and 37, Uguzzoli et al. teach the donor and acceptor dyes are within 25 nucleotides of one another (see p. 145 Table 1)

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With regard to claim 29, Uguzzoli et al. teach the donor is fluorescein and the acceptor is (see p. 145 Table 1)

With regard to claim 38, Uguzzoli et al. teach analyzing a SNP site of a nucleic acid wherein said pair of probes comprises a monomeric LNA moiety that is positioned opposite to the SNP site subsequent to the hybridization of the probes with the analyte (see the abstract and p. 146 col. 1 under *Detection of the β<sup>A</sup> and β<sup>S</sup> allelic variants with a two color 5' nucleoase assay*).

#### ***Summary***

4. No claims were allowable.

#### ***Correspondence***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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/Heather G. Calamita/  
Examiner, Art Unit 1637